PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)	
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2004/042792	17.12.2004	17.12.2003

International Patent Classification (IPC) or both national classification and IPC
A61N1/372, A61N1/36, A61N1/08, A61N1/39

Applicant
MEDTRONIC PHYSIO-CONTROL CORP.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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IAP12 Rec'd PCT/PTO 16 JUN 2006

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2004/042792

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 7-19

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 7-19

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-6

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-6
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-6
Industrial applicability (IA)	Yes:	Claims	1-6
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item IV.

The separate groups of inventions are:

Claims 1-6 :
A patient parameter monitoring pod, comprising :
a portable housing,
a patient parameter module connectable to the patient through lead cables,
a transceiver to communicate wirelessly to a defibrillator,
and a data port to supply the patient data via a direct electrical connection to the defibrillator

Claims 7-12 :
A patient parameter monitoring pod, comprising :
a housing holding a power supply;
patient lead cables attachable between the patient and the housing,
a carrying handle positioned to protect the patient lead cable port and the patient lead cables attached to the port from direct impact.

Claims 13-19 :
A patient monitor pod system, comprising :
a portable patient monitoring pod,
a component bag,
a patient parameter module,
a data port,
wherein the component storage bag has pockets for holding the pod and components of the pod, the storage bag has openings exposing the data port and permits passage therethrough the patient lead cables.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons: the common subject matter of the three groups of inventions is :
a patient monitoring pod, comprising :
a housing,
patient lead cables attached between a patient and the housing to collect patient data, the

patient data including at least one vital sign.

These features are all disclosed in document US-A-5 105 821. For this reason, there is no unity between claims 1, 7 and 13.

Re Item V.

1 Reference is made to the following documents:

D1 : EP 1 228 782 A (ST. JUDE MEDICAL AB) 7 August 2002 (2002-08-07)
D2 : US 4 096 856 A (SMITH ET AL) 27 June 1978 (1978-06-27)
D3 : US 5 105 821 A (REYES ET AL) 21 April 1992 (1992-04-21)
D4 : EP 1 250 944 A (GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC) 23 October 2002 (2002-10-23)

2 INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of **claim 1 does not involve an inventive step** in the sense of Article 33(3)PCT.

Document D3, which is considered to represent the most relevant state of the art to the subject matter of claim 1, discloses (the references in parentheses applying to this document): a patient parameter monitoring pod, comprising:
a **portable housing** (housing of element 14, figure 1) containing a power supply;
a **patient parameter module** (element 14, figure 1) connectable to a patient via **lead cables** (leads connected to elements 39, figure 1) to collect patient data, the patient data including at least one vital sign;
and a **data port** (input connector 38, figure 1) adapted to supply the patient data via a direct electrical connection to the defibrillator (defibrillator 12, figure 1).

The subject-matter of independent claim 1 differs from the disclosure of D3 in that the patient parameter monitoring pod further comprises a **transceiver** adapted to

wirelessly transmit the patient data to a defibrillator.

The problem to be solved by the present invention may therefore be regarded as **enabling the distance-communication between the pod and the defibrillator.**

In view of D1 the solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
D1 discloses the same kind of apparatus of the one described in claim 1. In D1, the patient parameter monitoring pod (element 2, figure 1) comprises a transceiver (element 8, figure 1) adapted to wirelessly transmit the patient data to a defibrillator (element 4, figure 1).

Therefore the features disclosed in D1 and D3 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 1 thus cannot be considered inventive (Article 33(3) PCT).

3 **Dependent claims 2-6** contain either features known per se from the prior art or being simple constructional features. Thus they would only satisfy Art. 33(2),(3) PCT when referring to a patentable independent claim.

4 In order to facilitate the examination of the conformity of the amended application with the requirements of Art. 34(2)(b) PCT, the applicant is requested to **clearly identify the amendments carried out**, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.